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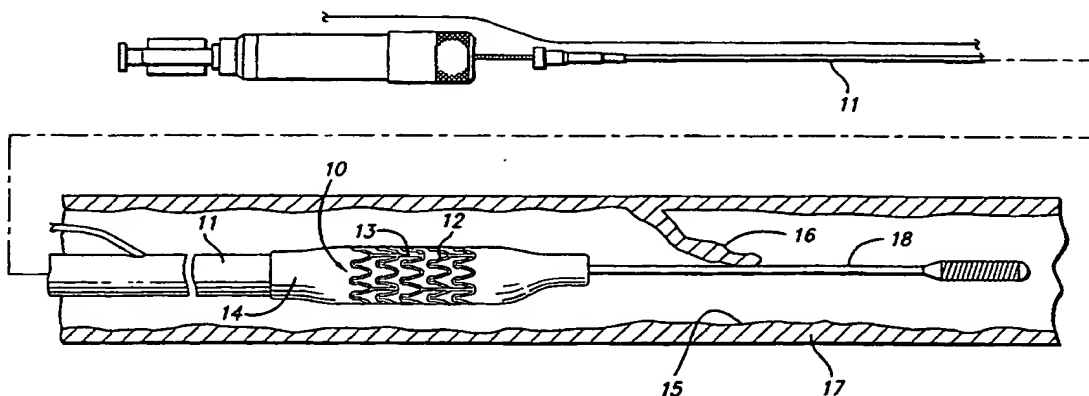
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **CEREBRAL VASCULATURE STENT**



(57) Abstract: An improved expandable stent for implantation in a body lumen, such as an artery and in particular for use in neurovasculature. The stent (10) consists of a plurality of radially expandable cut cylindrical elements (12) or rings generally aligned on a common axis and interconnected by one or more interconnective elements (13), in a manner to optimize flexibility and to achieve desired transitions in flexibility. The individual radially expandable circumferentially extending elements (12) are disposed in an undulating pattern and the overall stent pattern provides a structure that is visible by such methods as fluoroscopy.

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CEREBRAL VASCULATURE STENT

RELATED APPLICATION

This application is based upon and claims priority to the provisional application Serial No. 60/164,810 filed November 10, 1999 entitled Cerebral Stent.

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BACKGROUND OF THE INVENTION

This invention relates generally to repair devices which are adapted to be implanted into a patient's body lumen to maintain the patency of the lumen and
10 more particularly, to employing stents to treat narrowed, occluded, or weakened blood vessels.

In the medical arts, stents are generally tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use to support and hold back a dissected arterial lining
15 which can occlude the fluid passageway or to otherwise hold open and enlarge vessels occluded with debris.

Various means have been provided to deliver and implant stents for the purpose of repairing narrowed or weakened vessels. One method frequently described for delivering a stent to a desired intraluminal location includes mounting
20 the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter.

25 It has become desirable to perform such procedures in the cerebral vasculature to open vessels that are narrowed by fibrins, platelets, plaque or calcium or to protect weakened vessels such as those suffering from aneurysms. Due to the

threat of stroke and the need to maintain blood flow to the brain, it is particularly desirable to treat such vessel abnormalities as expediently and effectively as possible.

Since the cerebral vasculature is characterized as being highly tortuous as well as easily pierced in response to forces applied thereto, placement of stents within the cerebral vasculature has proven to be a significant challenge. That is, in view of the inherent characteristics of cerebral vasculature, access in itself, is a main factor to consider when contemplating delivering stents for the purpose of repairing diseased sections. Accordingly, a stent contemplated for use in repairing diseased sections of cerebral vasculature must be flexible enough to be navigated through tortuous pathways without piercing vessel walls during its advancement and have sufficient radial and axial strength when deployed to completely repair the vessel.

It is also important to minimize radial forces generated during deployment of a stent within cerebral vasculature. Accordingly, a stent for use in cerebral vasculature should embody structure that allows it to be expanded in response to relatively low deployment pressures so that trauma to vessel walls can be minimized.

Moreover, since cerebral vasculature is also characterized by having numerous small blood vessels, referred to as perforators, branching from main pathways and since such perforators often provide the only blood source to a particular part of the brain, accurate placement of a stent within cerebral vasculature (i.e., intracranially) is highly critical. The skull, however, acts as a visual barrier when placing stents within vessels deep within the cerebral vasculature. Thus, it is necessary that the stent embody sufficient radiopacity so that it can be viewed by methods such as active fluoroscopy so that accurate placement may be accomplished. However, simply adding mass to the stent can adversely affect its ability to navigate the tortuous pathways leading to the diseased portion of the cerebral vasculature.

Uniformity of stent expansion and minimization of axial shortening of a stent during expansion are also important objectives when considering repair of cerebral vasculature. That is, since accurate placement of a repair device in cerebral

vasculature is highly critical, predictable expanded profiles of stents are desirable. Additionally, offsetting opposing forces which are typically applied to the ends of a stent during conventional balloon expansion, such forces tending to shorten the stent, is also a concern in light of the necessity of accurate placement of a stent in cerebral vasculature.

Accordingly, what is needed and heretofore unavailable is a repair device that can be navigated through tortuous vasculature, that has sufficient radial strength and which embodies structure that facilitates accurate placement within diseased vasculature. The present invention satisfies these needs and others as will be apparent to the ordinary skilled artisan.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides a repair device characterized by having sufficient flexibility to navigate highly tortuous vasculature and the radial strength necessary to repair diseased portions of vasculature. The repair device of the present invention also possesses sufficient radiopacity so that accurate placement is possible. Moreover, the repair device of the present invention expands uniformly in response to a relatively low deployment pressure and embodies structure which tends to minimize axial shortening during expansion.

The repair device of the present invention is contemplated to be a generally tubular stent that includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. Preferably, the individual radially expandable rings or circumferentially extending or cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own expanded diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and prevent warping of the stent when it is expanded. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, but not so close as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively providing a stent which is flexible along its length and about its longitudinal axis, but is still very stiff in the radial direction in order to resist collapse.

Moreover, it is contemplated that the repair device embody sufficient mass for radiopacity purposes, while maintaining desired flexibility. To achieve this,

a balance can be struck between these factors by varying for particular applications, local strut width and thickness.

The aforescribed stents generally have a precisely laid out circumferential undulating pattern, e.g. serpentine. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern similar to changes in a waveform which result from decreasing the amplitude and the frequency of the waveform. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded so that the stent will remain in the expanded condition and, therefore, they must be sufficiently rigid when expanded to prevent their collapse in use. During expansion of the stent, portions of the undulating pattern may tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

The elongated elements which interconnect adjacent cylindrical elements should have a precisely defined transverse cross-section, the same can be similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. Alternatively, the width and thickness of the connecting members can be varied and be distinct from that of the cylindrical elements. The interconnecting elements are formed as a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element. Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. By circumferentially aligning certain of the interconnecting members, shortening of the stent upon expansion is minimized.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded, as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In one presently preferred embodiment, the stent pattern consists of a six (6) crown design that is made up of five (5) cylindrical elements or rings. In the five (5) ring design, there are four (4) circumferential areas between rings where connecting links are positioned. In this pattern, the end rings both at the first and the second end of the stent are designed to have two connecting links. In the medial portion of the stent, there is only a single connecting link per ring. This design approach causes the stent to resist shortening during balloon expansion while transitioning to more flexibility in the middle of the stent. Having this type of transition profile along the length of the stent is beneficial during access due to the flexibility required in accessing the tortuous cerebral anatomy. Additionally, the two body rings that contain a single connecting element are oriented circumferentially in the pattern so that they are in-line with one of the connecting elements in each of the end rings. These in-line connecting elements are circumferentially oriented 180 degrees apart from one another from the first end to the second end of the stent. This design feature helps provide axial stiffness during stent expansion, which is necessary to have uniform expansion with minimal shortening.

In another presently preferred embodiment, the stent pattern consists of a six (6) crown design that is made up of ten (10) cylindrical elements or rings. This pattern of interconnecting members is defined by an alternating series of two (2) and one (1) connecting links, where there are two connecting links between rings positioned at terminal ends of the device and the rings positioned longitudinally

adjacent thereto, respectively. The locations of the connecting elements are selected to resist shortening without sacrificing flexibility.

The repair devices incorporate a fine precision structure cut from a very small diameter, thin-walled cylindrical tube. In this regard, it is extremely important to make precisely dimensioned, smooth, narrow cuts in the stainless steel tubes in extremely fine geometries without damaging the narrow struts that make up the repair device structure. Thus, it is contemplated that the repair device of the present invention be cut from a tube by a laser.

The above and other objects and advantages of this invention will be apparent from the following more detailed description when taken in conjunction with the accompanying drawings of exemplary embodiments.

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged lumen;

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged lumen, pressing the damaged lining against the arterial wall;

FIG. 3 is an elevational view, partially in section showing the expanded stent within the lumen after withdrawal of the delivery catheter;

FIG. 4 is a perspective view of a stent embodying features of the invention in a partially expanded state;

FIG. 5 is a plan view of an unrolled section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. 4;

FIG. 5a is a sectional view taken along the line 5a-5a in FIG. 5;

FIG. 6 is a plan view of an unrolled section of an alternative embodiment of a stent pattern of the present invention;

FIG. 7 is a plan view of an unrolled section of another alternative embodiment of a stent pattern of the present invention;

FIG. 8 is a schematic representation of equipment for selectively cutting the tubing in the manufacture of stents, in accordance with the present invention;

FIG. 9 is an elevational view of a system for cutting an appropriate pattern by laser in a metal tube to form a stent, in accordance with the invention;

FIG. 10 is a plan view of the laser head and optical delivery subsystem for the laser cutting system shown in FIG. 9;

FIG. 11 is an elevational view of a coaxial gas jet, rotary collet, tube support and beam blocking apparatus for use in the system of FIG. 8;

FIG. 12 is a sectional view taken along the line 12-12 in FIG. 11;

FIG. 13 is an elevational and schematic drawing of laser beam diameter vs. spot size and depth of focus; and

FIG. 14 is an elevational and schematic drawing of focal length vs. spot size and depth of focus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and particularly FIG. 1 thereof, there is shown a repair device of the present invention. The repair device advantageously
5 embodies sufficient axial flexibility so that it can be transported through highly tortuous pathways as well as ample radial strength for repairing diseased lumens. Moreover, the repair device expands in response to relatively smaller radial pressures than coronary artery stents and embodies structure to not only minimize axial shortening during expansion but to provide the device with adequate radiopacity.
10 Thus, the repair device can be accurately placed when endeavoring to repair body lumens, particularly in the cerebral vasculature, more particularly in the anterior cerebral arteries, middle cerebral arteries and posterior cerebral arteries..

It is contemplated that the repair device of the present invention embody a stent 10 which is mounted onto a delivery catheter 11. The stent 10 is a high
15 precision patterned tubular device. The stent 10 typically comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within a lumen 15 (for example an artery or vein). The lumen 15 has been
20 shown as including a dissected lining 16 which has occluded a portion of the arterial passageway, however, the present invention is also contemplated to repair other forms of occlusions such as plaque as well as to repair aneurysms.

The typical delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty
25 procedures. The balloon 14 may be formed of suitable materials such as polyether-etherketone (PEEK), polyether block amide (PEBAX), polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent 10 to remain in place on the balloon 14 during delivery

to the site of the damage within the lumen 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve (not shown) may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon. Moreover, heat and/or pressure may be employed to mount a stent on a balloon catheter. That is, the stent 10 can be placed on the balloon 14 of the delivery catheter 11 and temporarily covered with a sleeve (not shown). The assembly or balloon portion itself may then be heated which causes expansion of the air in the balloon 14 to thereby increase the engagement between the balloon 14 and the stent 10. In addition, the balloon 14 itself can be slightly expanded to also increase the engagement between the stent 10 and balloon 14. Thereafter, the sleeve can be removed.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g. stepped or tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown) in the femoral artery. A guidewire 18 is disposed across the damaged luminal section with the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the lumen 15 until the stent 10 is directly under the detached lining 16. It is to be recognized that although the drawing figures show the repair of a lumen with a detached or dissected lining, the present invention is also contemplated to be used to treat plaque lesions or other forms of stenoses or blockages. In use, the balloon 14 of

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the catheter is expanded, expanding the stent 10 against the lumen 15, which is illustrated in FIG. 2. While not shown in the drawing, the lumen 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of a lumen, the lumen may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the lumen 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the lumen 15 and as a result do not interfere with the blood flow through the lumen 15. The cylindrical elements 12 of the stent 10 which are pressed into the wall of the lumen 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the lumen. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the lumen 15, and consequently are well adapted to tack up and/or hold back other sclerotic plaque or other material and hold in place small flaps or dissections in the wall of the lumen 15, as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1. As best seen in the flat pattern of the cylindrical stent having been unrolled (FIG. 5), the stent pattern consists of a six (6) crown 20 design that is 8 mm in length prior to expansion and is made up of five (5) cylindrical elements or rings 12. By design, five (5) rings have only four (4) circumferential areas between rings where connecting links can be used. In this pattern, the end rings both at the first 22 and the second 24 end of the stent are designed having two connecting links 13 relative to the adjacent rings. At the medial region 26 of the body of the stent, there is only a single connecting link 13 per ring 12. This design approach causes the stent 10 resist

shortening during balloon expansion at the ends 22, 24 while transitioning to more flexibility in the middle of the stent 10. Having this type of transition profile along the length of the stent 10 is beneficial during access due to the flexibility required in accessing the tortuous cerebral anatomy.

5 Moreover, embodying two connecting links 13 near the end portion 22, 24 of the stent 10 tends to facilitate effective deployment of the stent 10 within a body lumen. To wit, the multiple connecting links 13 at the ends of the stent provides the stent 10 with greater radial strength at its ends and thus aid in anchoring the stent 10 at a repair site.

10 Additionally, the two cylindrical elements or rings 12 that contain a single connecting element 13 are oriented circumferentially in the pattern so that they are in-line with one of the connecting elements in each of the end rings. These in-line connecting elements are circumferentially oriented 180 degrees apart from each other and in-line with connecting links of each end ring. This design feature helps provide
15 axial stiffness or desirable column strength during stent expansion, which is necessary to have uniform expansion with minimal shortening.

 That is, during conventional balloon expansion, the end portions of the balloon 14 which do not engage the stent 10 expand more quickly and readily since there is less of a restraint on these portions of the balloon 14. By assuming this
20 expansion profile, the balloon 14 consequently generates opposing longitudinally directed forces on the ends 22, 24 of the stent 10 which tend to cause the stent 10 to shorten. By circumferentially aligning one or more of the connecting elements 13, or by otherwise placing the connecting elements in a manner to minimize the circumferential angle therebetween, the resultant stent 10 has enhanced column
25 strength for offsetting such opposing forces to thereby minimize axial shortening. Similarly, by positioning certain of the connecting elements 180° apart, a degree of column strength can be achieved while maintaining a desired transition in axial flexibility to navigate tortuous vasculature.

Therefore, the pattern of connecting elements 13 is selected to provide the stent 10 with desirable structural characteristics, one that does not adapt a simple spiral pattern of connecting elements as seen in the prior art. That is, simply spiraling connecting elements along a stent would conceivably do less to provide a desired degree of column strength at a particular location of the stent while maintaining desired transition in flexibility. To wit, when subjected to a columnar load, a stent embodying a simple spiral pattern of connecting elements may tend to twist about a longitudinal axis.

In a preferred embodiment, the stent 10 is formed from an approximately .070 inches (1.78 mm) 316L stainless steel tube with a wall thickness of about .0048 to .0060 inches (.12 - .15mm). The expansion range is about .098-.177 inches (2.5 - 4.5mm) with a maximum expansion diameter of approximately .21 inches (5.3 mm). A stent strut has a width of approximately .0030 to .0037 inches (.076 - .093 mm) and a thickness of .0048 to .0050 inches (.12 - .13 mm). Prior to expansion, the stent 10 has a length of about .31 inches (8 mm). At an expanded diameter of .12 inches (3.0 mm), the length of the stent is about .30 inches (7.7 mm) and at a .18 inches (4.5 mm) expansion, the length of the stent is approximately .25 inches (6.5 mm). Thus, upon radial expansion, the stent 10 shortens less than about twenty percent (20%) and when expanded to .12 inches (3.0 mm), the device shortens in length approximately 5.3 percent (5.3%). Also, the device 10 may recoil approximately 2.5%. In one aspect, the stent free area is approximately 88% at .12 inches (3.0 mm).

The average radial strength of the stent 10 is approximately 9.60 PSI. The interconnecting element pattern results in a stent 10 which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent 10 during the expansion thereof.

The resultant stent 10 has sufficient mass such that due to its radiopacity, the stent 10 is visible by remote imaging techniques such as fluoroscopy even when placed into vasculature within the skull of a patient. Significantly, in varying the local strut widths (.0030 to .0037 inches , for example) and thickness
5 (.0048 to .0050, for example), a desired balance between the required radiopacity and flexibility can be achieved. One or more of selected struts can embody sufficient mass for radiopacity purposes while overall flexibility of the stent 10 can be maintained. Materials that enhance radiopacity can also be applied to the stent. Moreover, the stent 10 possesses the desired flexibility for transportation through
10 tortuous pathways as well as variable flexibility, and desired transitions in flexibility, along its length. Further, the resultant stent 10 also embodies the desired radial strength to successfully treat narrowed or occluded lumens.

Referring now to FIG. 6, there is shown another preferred embodiment 30 of the present invention. This embodiment also contemplates six (6) crowns 32
15 and a five (5) cylindrical element or ring 33 design. In this preferred embodiment, the stent pattern is characterized by being stiffer in the middle 34 of the stent 30 and transitions to more flexible on the ends 36, 38. Specifically, there are three connecting links 39 in the middle 34 of the stent 30 and one connecting the end rings. This approach can be beneficial, depending on your delivery system design, to help
20 create smoother stent to delivery system transitions which allow for the device to have better deliverability. Additionally, this configuration also provides more coverage or scaffolding in the middle of the stent which is particularly desirable where the plaque burden is the greatest in that area or to cover the opening into an aneurysm. Softer or more flexible ends may also allow for better stent to delivery system transition.

25 In another preferred embodiment 40 (FIG. 7), the repair device of the present invention embodies a six (6) crown 42 and a ten (10) cylindrical element or ring 43 design. This embodiment is characterized by a pattern of an alternating series of two and one connecting links 44 between longitudinally adjacent rings 43. The pattern begins with two connecting links 44 between a ring 43 defining a terminal end

46 of the device and a ring 43 positioned longitudinally adjacent thereto and continues in the alternating pattern of one and two links between adjacent rings 43. This stent 40 is contemplated to be used to repair relatively longer sections of vasculature while balancing desired flexibility and resistance to axial shortening. In particular, by offsetting the connecting links 44 by a single crown and thus approximating an in-line arrangement, the connecting links cooperate to minimize shortening.

In one aspect of the invention, the connecting links 44 are arranged in a non-helical pattern along the stent 10. As shown in the figures, connecting link 44 can be configured to connect a W-shaped member 52 to a Y-shaped member 53. Where the stent 10 embodies a six crown design (See FIG. 5 for example) and the connecting member 44 is configured between the W-shaped 52 and Y-shaped members 53, there are six quadrants or circumferential sections at which the connecting members 44 can be positioned. In a stent 10 embodying connecting links arranged in a non-helical pattern, a connecting link 44 between a first pair of adjacent circumferentially extending elements or rings 12 can be offset circumferentially by at least one quadrant section from a connecting link between a second pair of adjacent circumferentially extending element or rings 12.

More generally, in a stent 10 that can be sectioned into six circumferentially quadrants for example, connecting elements positioned between a first pair of longitudinally arranged rings or cylinders is offset circumferentially more than sixty degrees from a connecting element between an adjacent pair of longitudinally arranged rings or cylinders. Moreover, it is contemplated that connecting elements in a non-helical pattern can be positioned varying degrees circumferentially between one pair of rings and another pair of rings. That is, a connecting element in a six quadrant stent can be located at a position designated zero degrees (0°) for example, a next adjacent set of rings having a connecting element positioned at sixty degrees (60°) and a third set of longitudinally adjacent rings having a connecting element positioned at one hundred eighty degrees (180°) or one

hundred twenty degrees (120°) from the immediately preceding pair of rings.

Multiple connecting links can be placed between adjacent rings to further distinguish the stent from a helical pattern of connecting links. It is to be recognized that a particular stent can be divided into fewer or more than six circumferential quadrants or sections and have a non-helical pattern of connecting elements and that the
5 example of a offsetting connecting link by multiples of sixty degrees (60°) has been provided for illustrative purposes only.

In yet another preferred embodiment of the present invention, the stent design employs connecting links having variable widths and thicknesses (not shown).

10 The use of variable sized struts provides a mechanism to achieve or intensify desirable transitioning from a stiff portion of the stent to a more flexible portion, and vice versa. The number of undulations may also be varied to accommodate placement of interconnecting elements 13, 39 and 44, for e.g., at the peaks of the undulations or along the sides of the undulations.

15 As shown in FIGS. 4 - 7, cylindrical elements 12, 33 are in the form of a serpentine pattern 50. As previously mentioned, each cylindrical element 12, 33, 43 is connected by interconnecting elements 13, 39, 44. Serpentine pattern 50 is made up of a plurality of generally U-shaped members 51, W-shaped members 52, and Y-shaped members 53, each having a different radius of curvature for example, so that
20 expansion forces are more evenly distributed over the various members.

In particular, the generally U-shaped members 51 are inverted with respect to the generally W-shaped 52 and Y-shaped 53 members. The U-shaped members 51 are further characterized by having an apex 54 with an enlarged radius of curvature from which the longitudinally extending arms 55 extend, the arms defining
25 an acute angle. Adjacent arms 55 of certain adjacent generally U-shaped members are shared by the W-shaped members 52 configured therebetween. Arms 55 of certain other adjacent generally U-shaped members are shared by the Y-shaped members 53 to thereby define the upper portion of a particular Y-shaped member, the bottom portion of which is provided by an interconnecting member 13, 39, 44.

The U, W and Y stent pattern provides structure that facilitates uniform expansion in response to a relatively low deployment pressure. By interspersing U-shaped members between W-shaped members 52 and by selectively positioning the Y-shaped members 53 along the length of the device, the repair device cannot only be
5 uniformly crimped on a delivery catheter, but upon expansion of the repair device, the U, W and Y-shaped members 51, 52, 53 open in a uniform manner.

Between adjacent U-shaped members 51 and at the base of the W-shaped members 52, there are dimples 56 formed in the members defining apices of each cylindrical element 12, 33. The dimples 56 provide the stent 10, 30, 40 with the
10 ability to be crimped down tightly on a catheter resulting in a very low crossing profile. That is, the dimples 56 provide a structure having increased plastic strain which translates into less elastic recoil upon crimping. The dimples 56 also provide a structure having longer arm length 55 than apices defined by simple turns. This longer arm length 55 provides a lever arm that requires a relatively lower radial force
15 (i.e., lower inflation pressures compared to the state of the art coronary artery stents) necessary to expand the stent 10, 30, 40. Consequently, a stent configured with dimples 56 has a greater range of expansion requiring lower radial forces (i.e., lower inflation pressures) to expand.

Additionally, the dimples 56 are designed to cooperate with the apices
20 54 defining the base of the U-shaped members 51. In particular, the distance laterally across the dimples 56 is designed to generally be the same as the lateral distance across the apices 54. By doing so, the apices and dimples 54, 56 cooperate to facilitate uniformity in collapsing and more smoothly expanding the stent 10, 30, 40.

Where the repair device of the present invention is intended to be used
25 to repair cerebral vasculature, it is important to minimize radial forces generated during expansion thereof. That is, since cerebral vasculature is easily pierced and dissected, a critical objective is to endeavor to avoid trauma to vessel walls at the repair site. Thus, it is contemplated that the repair device expand in response to relatively low radial pressures. To do so, the longitudinally extending portions of the

U's, W's and Y's are lengthened to a desirable degree. In particular, the repair devices of the present invention are generally configured to begin to open in response to pressures on the order of 4-5 atmospheres and that implantation of the device is completed in response to pressures of 6-8 atmospheres.

5 The aforescribed illustrative stent 10 and similar stent structures can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, such as nitinol or stainless steel tubing to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. In accordance with the
10 invention, it is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser as illustrated schematically in FIG. 8.

 The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.07 inches (1.7 mm) in the unexpanded condition, slightly less
15 than the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inches (2.54 mm) or more. The wall thickness of the tubing is about 0.0049 to .006 inches (.12 - .15 mm).

 Referring to FIG. 8, the tubing 61 is put in a rotatable collet fixture 62 of a machine-controlled apparatus 63 for positioning the tubing 61 relative to a laser
20 64. According to machine-encoded instructions, the tubing 61 is rotated and moved longitudinally relative to the laser 64 which is also machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube is therefore cut into the discrete pattern of the finished stent.

 The process of cutting a pattern for the stent into the tubing is
25 automated except for loading and unloading the length of tubing. Referring again to FIG. 8 it may be done, for example, using a CNC-opposing collet fixture 62 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 65 to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the Nd-YAG laser set-up of the

foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating.

Referring now to FIGS. 9-12 of the drawings, there is shown a process and apparatus, in accordance with the invention, for producing metal stents with a fine precision structure cut from a small diameter thin-walled cylindrical tube. Cutting a fine structure (0.0030" web width) requires minimal heat input and the ability to manipulate the tube with precision. It is also necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of about 0.060" to 0.080" and a wall thickness of 0.002" to 0.007" or more. These tubes are fixtured under a laser and positioned utilizing a CNC to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern, it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris free cut, a Q-switched Nd/YAG, typically available from Quantronix of Hauppauge, New York, that is frequency doubled to produce a green beam at 532 nanometers is utilized. Q-switching produces very short pulses (<100 nS) of high peak powers (kilowatts), low energy per pulse (≤ 3 mJ), at high pulse rates (up to 40 kHz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller, therefore increasing the power density by a factor of 4 times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that make up to stent structure. Hence, the system of the present invention makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both
5 circular and linear interpolation to be utilized in programming. Since the finished structure of the stent is very small, a precision drive mechanism is required that supports and drives both ends of the tubular structure as it is cut. Since both ends are driven, they must be aligned and precisely synchronized, otherwise the stent structure would twist and distort as it is being cut.

10 The optical system which expands the original laser beam, delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It is also necessary to block the beam as it cuts through the top
15 surface of the tube and prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate
20 polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.018" I.D.) is centered around the focused beam with approximately 0.010" between the tip of the nozzle and the tubing. The jet is pressurized
25 with oxygen at 20 psi and is directed at the tube with the focused laser beam exiting the tip of the nozzle. The oxygen reacts with the metal to assist in the cutting process very similar to oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent

burning by the beam and/or molten slag on the far wall of the tube I.D., a stainless steel mandrel (approx. 0.034" dia.) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

5 Alternatively, this may be accomplished by inserting a second tube inside the stent tube which has an opening to trap the excess energy in the beam which is transmitted through the kerf along which collecting the debris that is ejected from the laser cut kerf. A vacuum or positive pressure can be placed in this shielding tube to remove the collection of debris.

10 Another technique that could be utilized to remove the debris from the kerf and cool the surrounding material would be to use the inner beam blocking tube as an internal gas jet. By sealing one end of the tube and making a small hole in the side and placing it directly under the focused laser beam, gas pressure could be applied creating a small jet that would force the debris out of the laser cut kerf from
15 the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris can be easily removed.

In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Oxygen air is
20 used in this application since it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gas such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there is usually a tail of molten material that collects along the exit side of the gas jet that must be mechanically or chemically removed
25 after the cutting operation.

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approx. 0.0005") with the molten slag re-solidifying along the cut. This traps the cut out scrap of the pattern requiring further processing. In order to remove the slag debris from the cut allowing the scrap to be removed from

the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCL for approximately 3 minutes at a temperature of approximately 180° F. Before it is soaked, the tube is placed in a bath of alcohol/water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. To prevent cracking/breaking of the struts attached to the material left at the two ends of the stent pattern due to harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning/scrap removal process. At completion of this process, the stent structures are rinsed in water. They are now ready for electropolishing.

The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110-135° F. The stents may be further treated if desired, for example by applying a biocompatible coating.

Referring now more particularly to FIGS. 13 and 14, it will be apparent that both focused laser spot size and depth of focus can be controlled by selecting beam diameter (FIG. 12) and focal length for the focusing lens (FIG. 14). It will be apparent from FIGS. 13 and 14 that increasing laser beam diameter, or reducing lens focal length, reduces spot size at the cost of depth of field.

Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and the like which produce pattern edges which are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are semi-square or semi-rectangular, rather than trapezoidal; see FIG. 5a. The resulting stent structure provides superior performance.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made

without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A device for repairing vasculature including vasculature within a skull of a patient, comprising:
 - a plurality of circumferentially extending members;
 - at least one longitudinally extending member between circumferentially
 - 5 extending members;
 - the circumferentially extending members and the longitudinally extending members defining a body; and
 - the body being dimensioned for placement and advancement within vasculature within the skull and having sufficient mass such that the body is visible
 - 10 when placed within vasculature covered by the skull using active remote imaging techniques.
2. The device of claim 1, further comprising a plurality of longitudinally extending members.
3. The device of claim 1, wherein the body has a length and a variable longitudinal flexibility along the length.
4. The device of claim 3, wherein the body includes a first end portion, a second end portion and a mid-section, the first and second end portions having a first axial flexibility and the mid-section having a second longitudinal flexibility.
5. The device of claim 4, wherein the first longitudinal flexibility is greater than the second axial flexibility.

6. The device of claim 3, wherein the longitudinal flexibility is varied by varying positioning of the plurality of longitudinally extending members.
7. The device of claim 3, wherein the longitudinal flexibility is varied by varying a total number of the plurality of longitudinally extending members.
8. The device of claim 3, wherein the longitudinal flexibility is varied by varying a cross-sectional profile of at least one of the plurality of circumferentially extending members.
9. The device of claim 1, wherein the device has an associated axial strength that can be varied.
10. The device of claim 9, wherein the axial strength can be varied by varying a total number of the plurality of longitudinally extending members.
11. The device of claim 9, wherein the axial strength can be varied by varying a cross-sectional profile of at least one of the circumferentially extending members.
12. The device of claim 9, wherein the device includes a first end portion, a second end portion, and a mid-section, the first and second end portions providing the device with greater axial strength than the mid-section.
13. The device of claim 1, wherein the device is expandable and has a first diameter, a second diameter, and a length; the device shortening less than approximately 25% in length when expanded to the second diameter.

14. The device of claim 1, wherein the device is expandable and has a first diameter and a length, the device shortening about 5 percent in length when expanded to a 3.0 mm diameter.

15. The device of claim 1, wherein the remote imaging technique is fluoroscopy.

16. The device of claim 1, wherein the device is expandable and begins to expand in response to a radially directed load of about 4 to 5 atmospheres.

17. The device of claim 1, wherein the device is expandable and fully expands in response to a radially directed load of about 6 to 8 atmospheres.

18. The device of claim 1, the circumferentially extending members defined by a pattern of alternating U-shaped members and W-shaped members.

19. The device of claim 1, wherein the U-shaped members deform more easily in response to a load than the W-shaped members.

20. The device of claim 1, wherein the circumferentially extending members are defined by an undulating pattern.

21. The device of claim 1, the body further comprising a first terminal circumferentially extending member, a second terminal circumferentially extending member and at least one circumferentially extending member defining a mid-section of the device.

22. The device of claim 21, wherein two longitudinally extending members extend between each of the first and second terminal circumferentially

extending members and an adjacent circumferentially extending member of the mid-section.

23. The device of claim 21, wherein a single longitudinally extending member bridges circumferentially extending members defining the mid-section.

24. The device of claim 21, wherein a pattern of longitudinally extending members bridging adjacent circumferentially extending members is defined by an alternating series of one and two longitudinally extending members.

25. The device of claim 21, wherein at least two the longitudinally extending members share a common longitudinal axis.

26. The device of claim 1, wherein the plurality of circumferentially extending members number five.

27. The device of claim 1, wherein the plurality of circumferentially extending members number ten.

28. The device of claim 1, wherein a cross-sectional profile of members defining the device is a rectangle having a height and a base.

29. The device of claim 28, wherein the height is greater than the base.

30. The device of claim 1, wherein the device is made from stainless steel 316L.

31. The device of claim 1, wherein the device includes a plurality of longitudinally extending members, the plurality of longitudinally extending members defining a non-helical pattern.

32. A device for repairing vasculature, comprising:
a plurality of circumferentially extending members arranged adjacent to each other, each circumferentially extending member assuming a generally serpentine pattern defining a plurality of apices, wherein selected apices embody dimples; and
at least one longitudinally extending member connecting adjacent longitudinally arranged circumferentially extending members.

33. The device of claim 32, wherein the dimples provide the device with structure having increased plastic strain which results in less elastic recoil upon crimping.

34. The device of claim 32, wherein the dimples provide the device with structure that facilitate crimping the device to smaller diameters and expand to a larger range of diameters with inflation pressures less than about 8 atmospheres.

35. The device of claim 32, the generally serpentine pattern has a first set of apices spaced longitudinally from a second set of apices.

36. The device of claim 35, wherein certain of the first set of apices embody dimples.

37. The device of claim 36, wherein the first and second set of apices each have an approximately equal lateral dimension.

38. The device of claim 32, wherein the dimples provide the device with longer longitudinally extending members than apices without dimples.

39. The device of claim 32, wherein the device includes a plurality of longitudinally extending members, the plurality of longitudinally extending members defining a non-helical pattern.

40. A stent consisting essentially of five rings having two links between the end rings and the next adjacent ring and a single link between each of the middle rings and configured to be implanted in an anterior cerebral artery, a posterior cerebral artery, a middle cerebral artery, or their connecting arteries.

FIG. 1

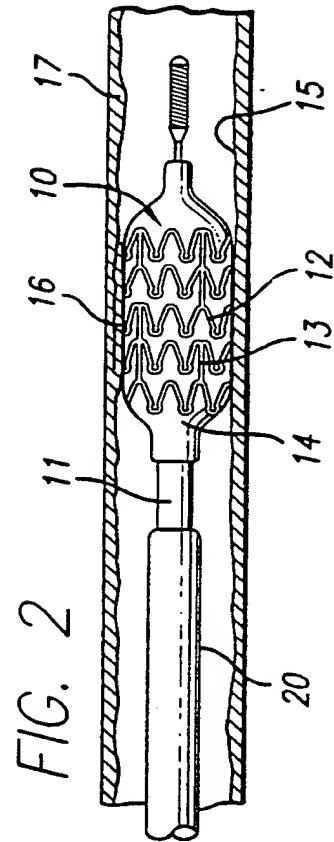
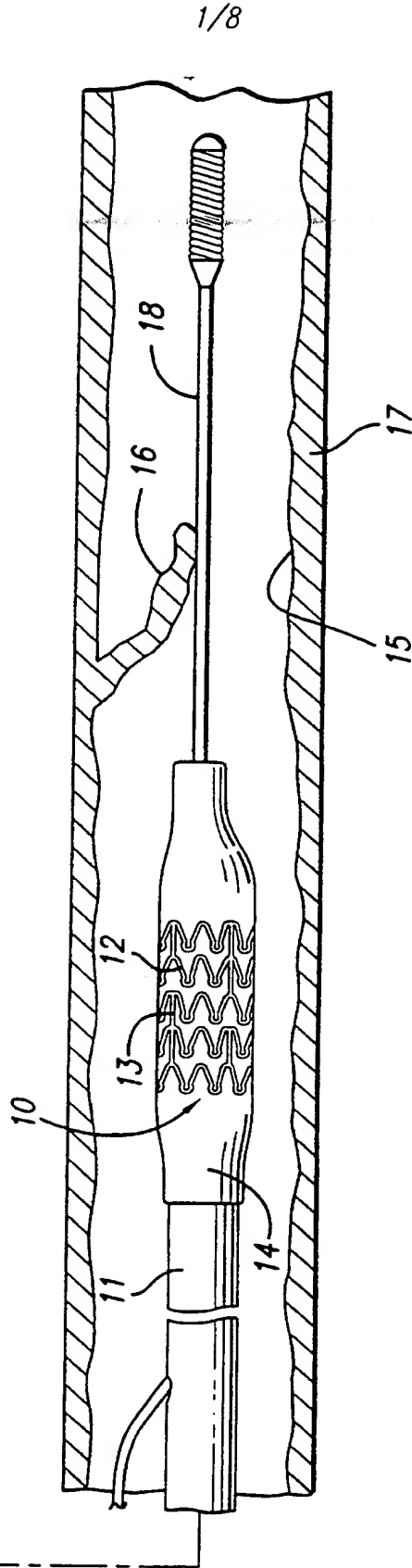
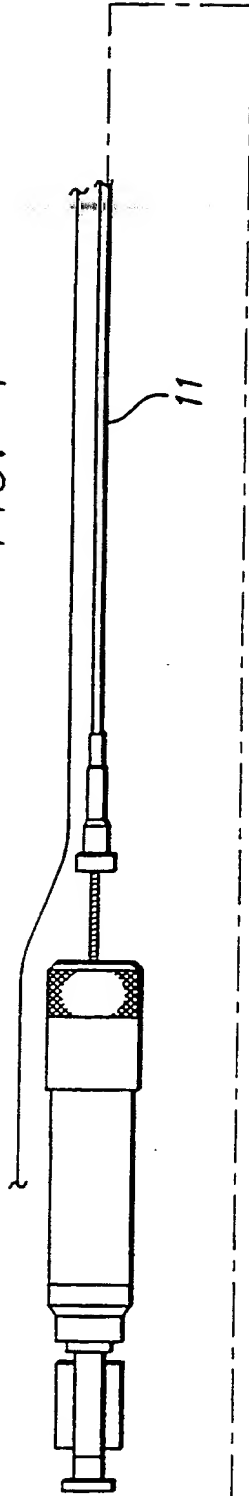


FIG. 2

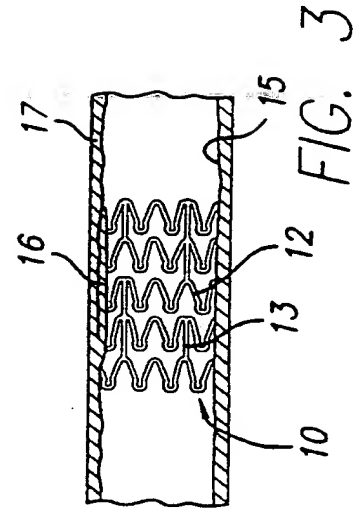


FIG. 3

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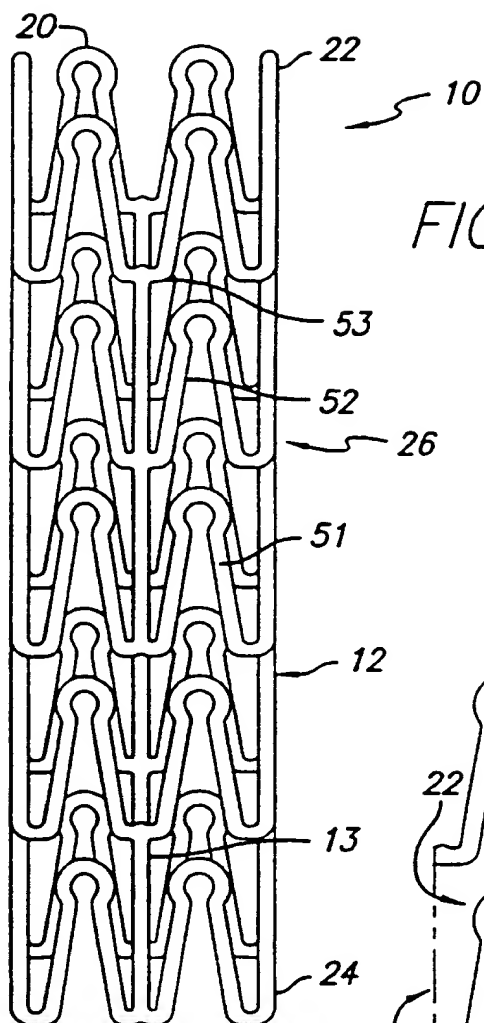


FIG. 4

FIG. 5

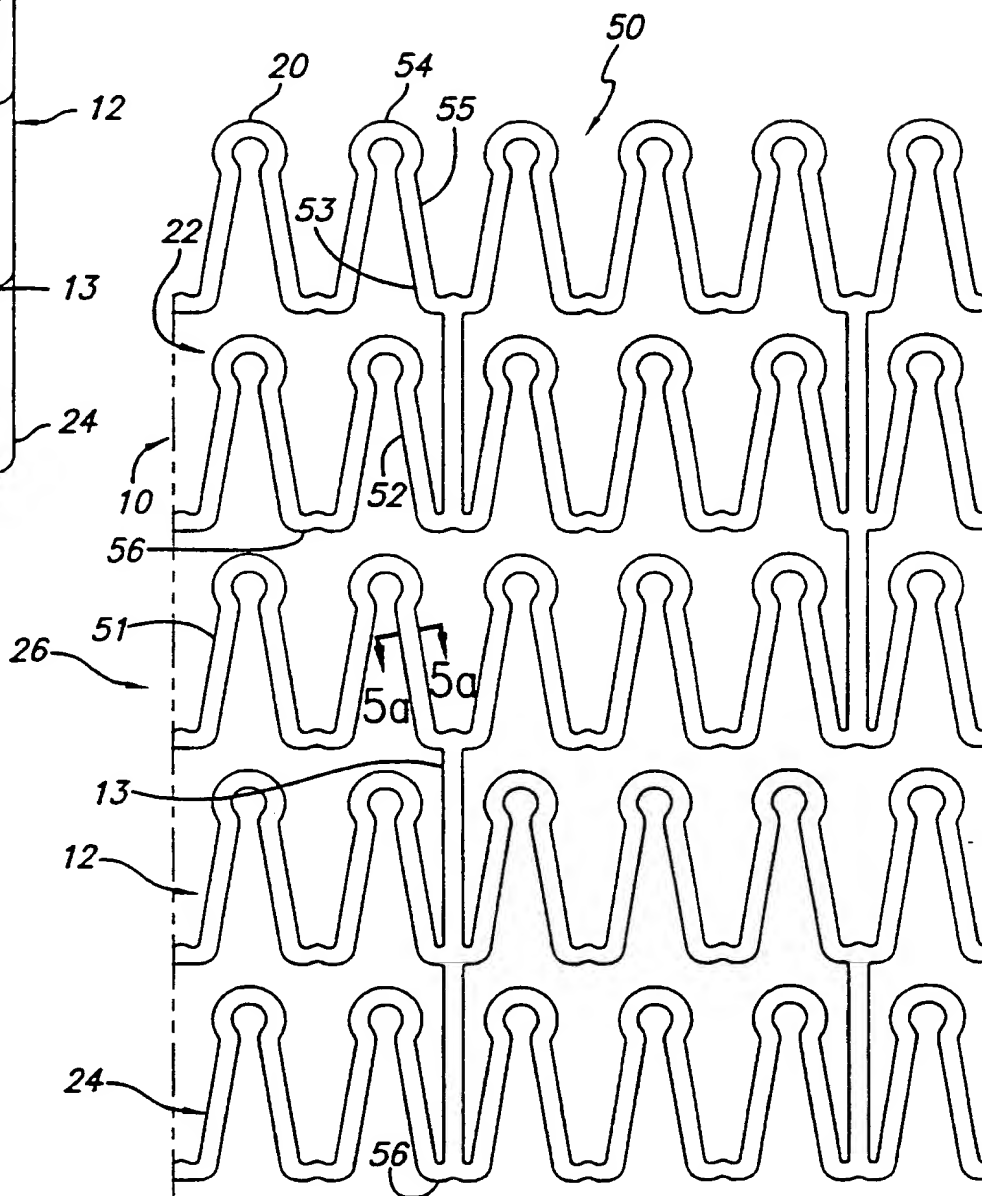
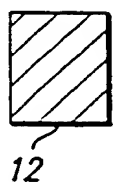


FIG. 5a



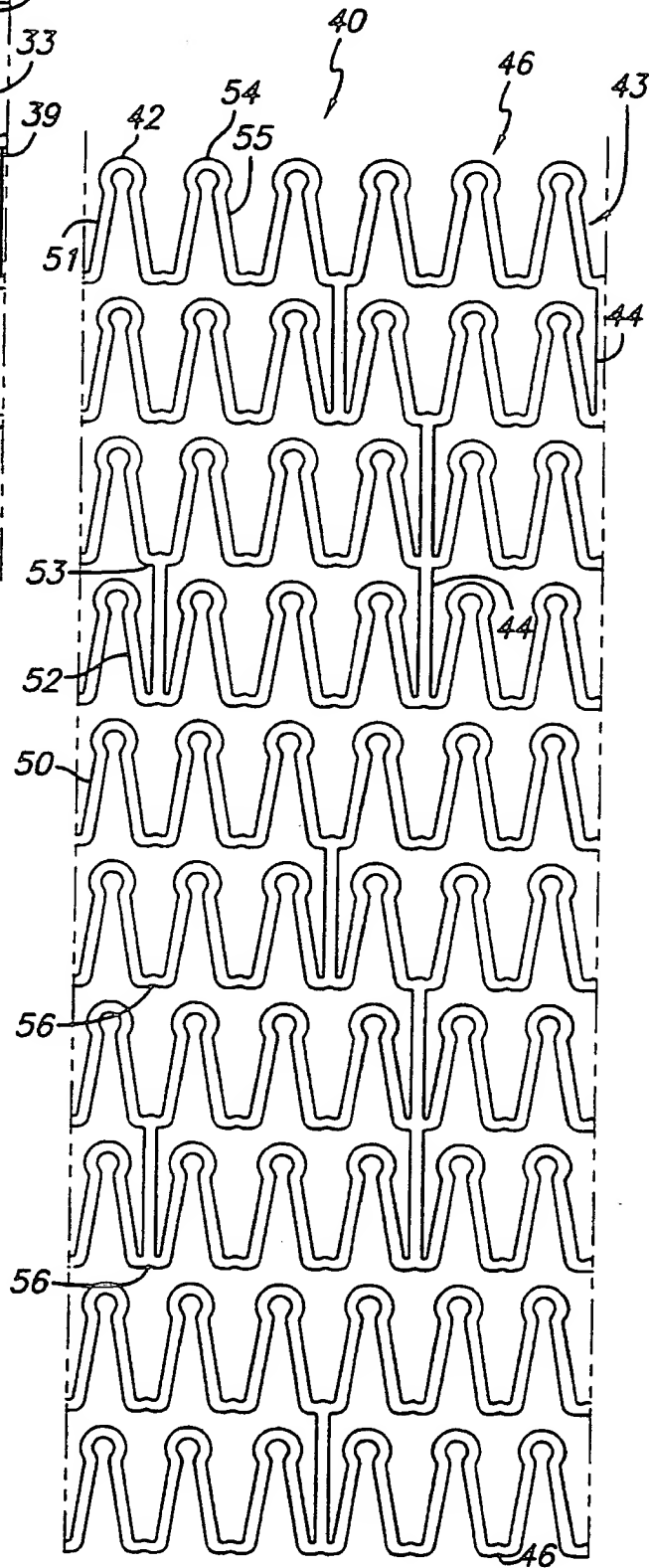
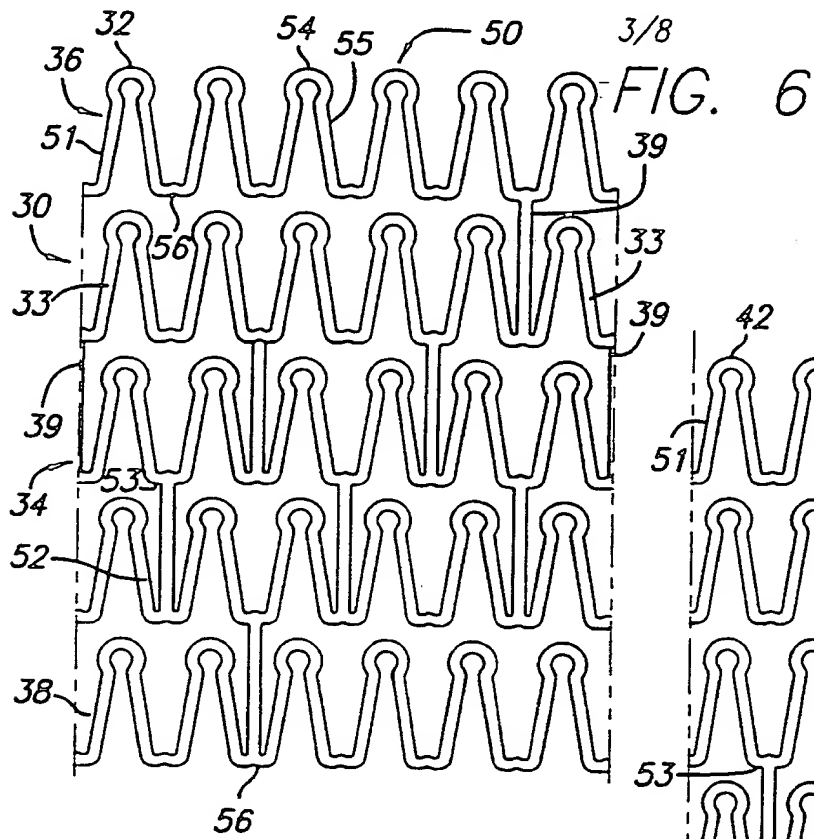


FIG. 7

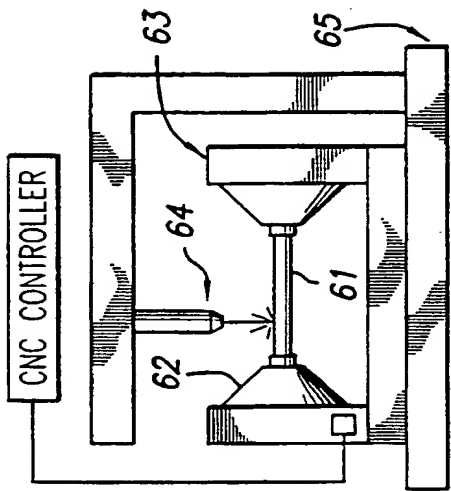


FIG. 8

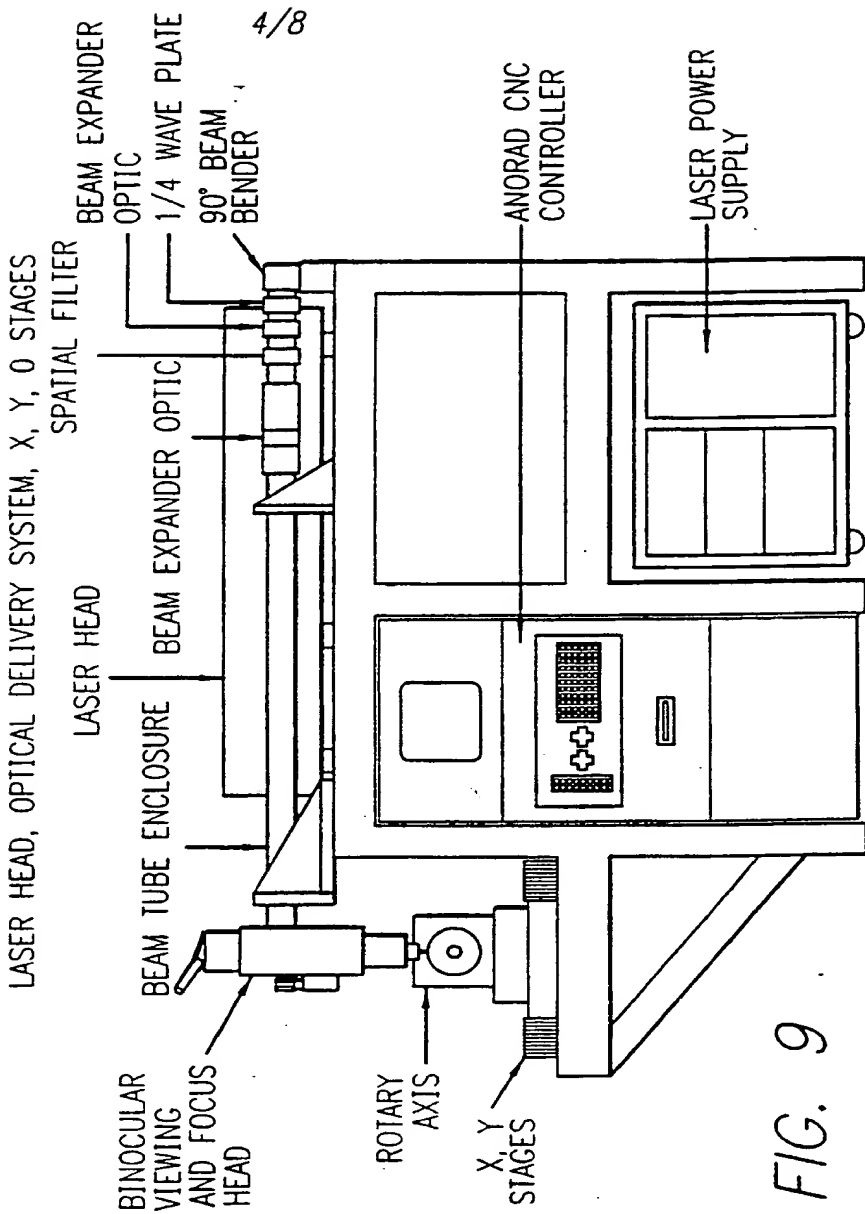
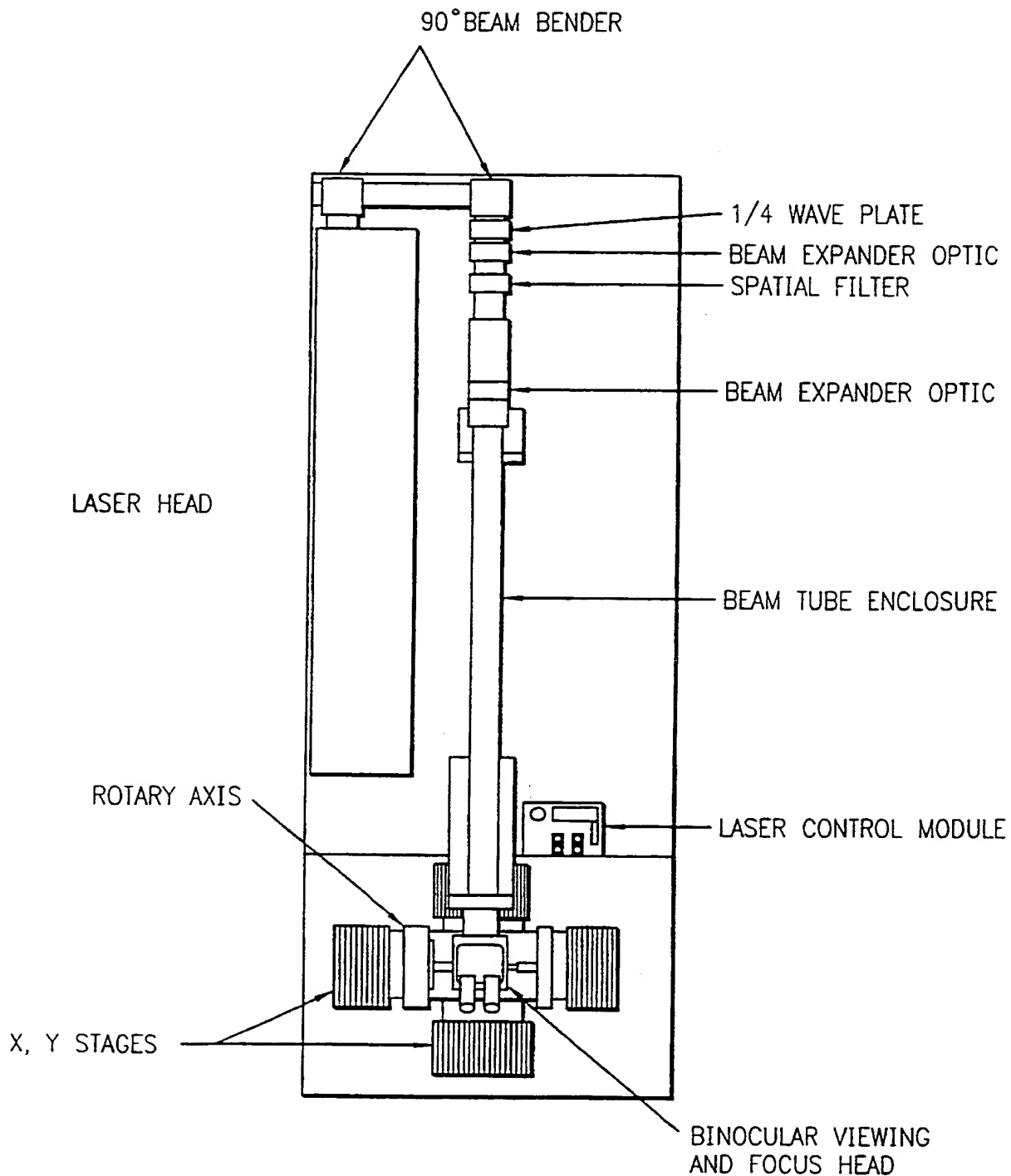


FIG. 9

FIG. 10

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LASER HEAD, OPTICAL DELIVERY SYSTEM, X, Y, Z STAGES



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FIG. 11

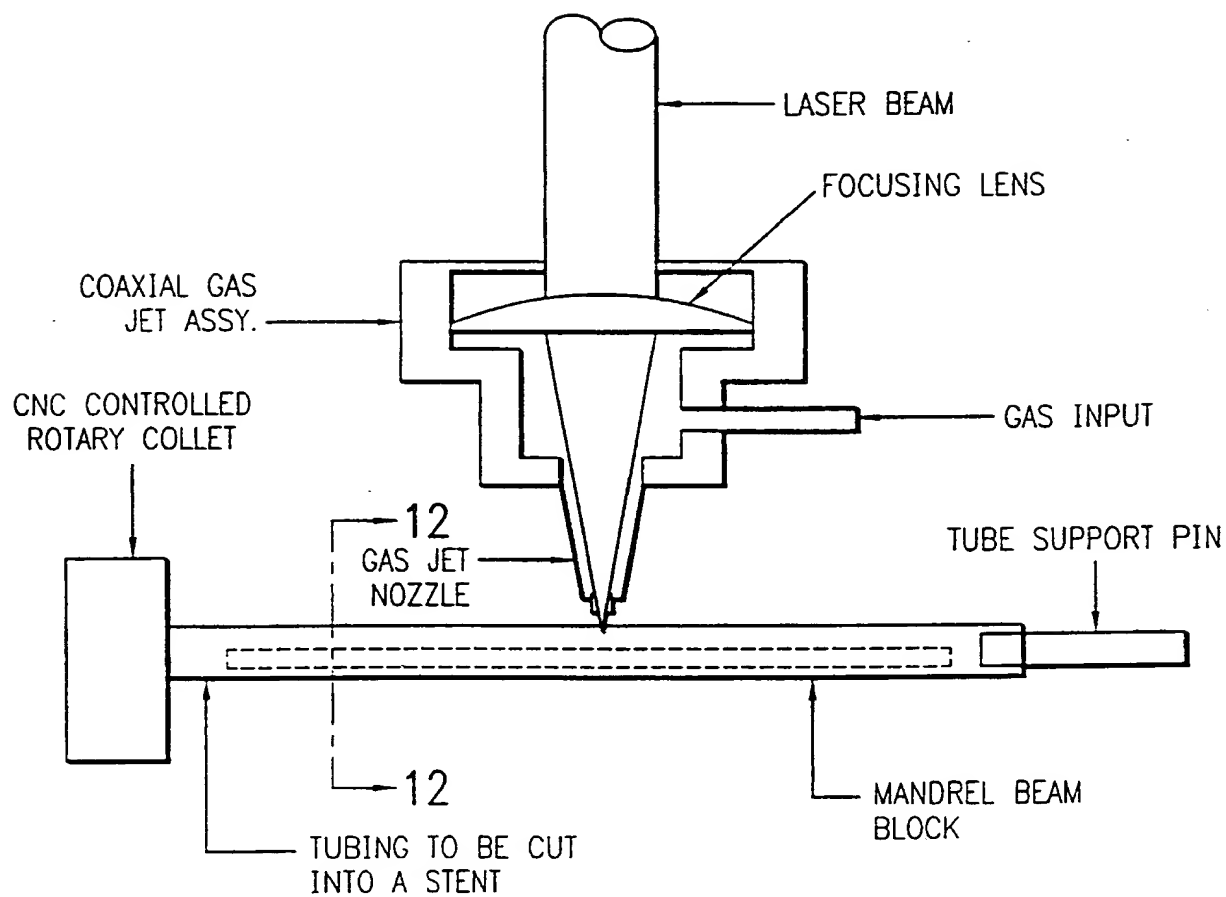
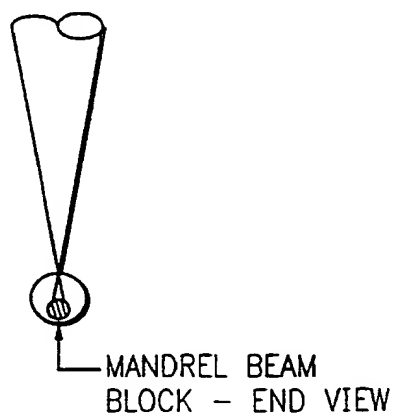
COAXIAL GAS JET - ROTARY COLLECT AND
TUBE SUPPORT - TUBE BEAM BLOCK

FIG. 12



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FIG. 13

BEAM DIAMETER VS SPOT SIZE AND DEPTH OF FOCUS

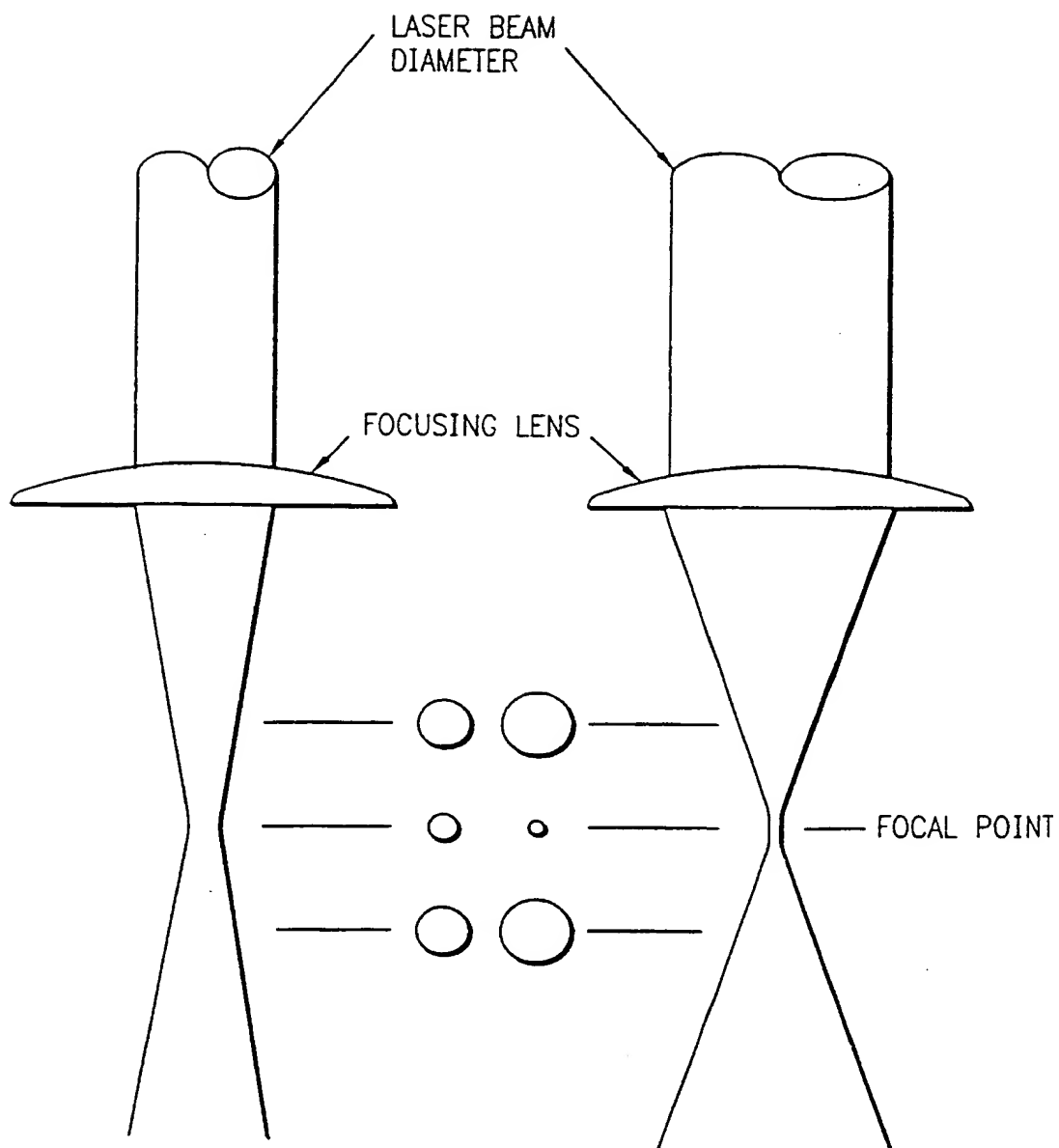
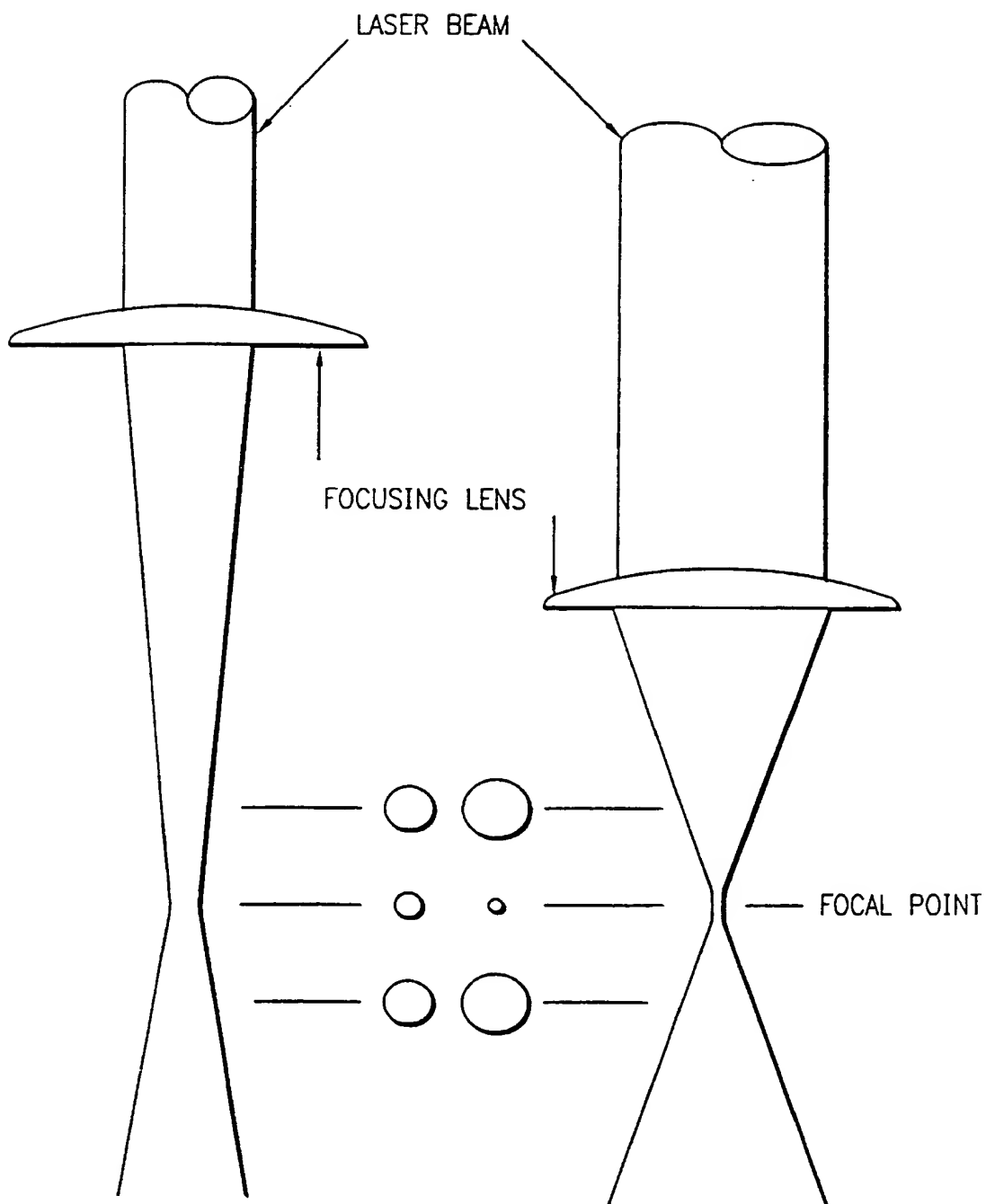


FIG. 14

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FOCAL LENGTH VS SPOT SIZE AND DEPTH OF FOCUS



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/30935

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 29/00

US CL : 623/1.16; 606/198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.16; 606/198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

East

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,556,414 A (TURI) 17 SEPTEMBER 1996, FIGS. 10-13	1-35 ----- 36-40
X --- Y	US 5,569,295 A (LAM) 29 OCTOBER 1996, FIGS. 1-7	1-35 ----- 36-40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 JANUARY 2001

Date of mailing of the international search report

05 FEB 2001

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